Long-term outcomes of secondary procedures after endovascular aneurysm repair

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Purpose: **This study evaluated the outcomes of secondary procedures after endovascular aneurysm repair (EVAR).**
Methods: **From 2002 to 2009, 1768 patients underwent EVAR for treatment of 1662 elective (94%) and 106 emergent (6%) infrarenal abdominal aortic aneurysm (AAA) with a variety of Food and Drug Administration-approved and commercially available stent grafts. Postoperative follow-up included clinical examination, pulse volume recording, duplex ultrasound imaging, and computed tomography and magnetic resonance angiography at 1, 6, and 12 months, and yearly thereafter. Patients with type I and III endoleaks, unexplained endotension, limb occlusion, stent graft migration, with and without type I endoleak, and aneurysm rupture underwent secondary interventions. Type II endoleak at >6 months without a decrease in the aneurysm sac underwent translumbar embolization. Data were prospectively collected.**
Results: **EVAR was performed in 1768 patients. During a mean follow-up of 34 (SD, 30.03) months, 339 patients (19.2%) required additional secondary procedures for aneurysm-related complications, including type I (n = 51, 15.0%), type II (n = 136, 40.1%), and type III (n = 5, 1.5%) endoleaks; endotension (n = 8, 2.4%), stent graft migration proximal fixation site (n = 46, 13.6%), stent graft iliac limb thrombosis or stenosis (n = 25, 7.4%), subsequent iliac aneurysm formation (n = 39, 11.5%), or aneurysm rupture after EVAR (n = 29, 8.6%). The mean age was 74 (SD, 9.15) years. Mean AAA size was 5.7 (SD 3.24) cm. Compared with secondary procedures for AAA rupture, the nonrupture patients had a significantly lower mortality (1.6% vs 17.2%, $P < .05$) and a higher likelihood of being managed by endovascular means (98.8% vs 44.8%, $P < .05$). When nonruptured EVAR patients required urgent secondary procedures for type I endoleaks and stent graft migration or limb thrombosis, the mortality was 6.0% vs 0.5% for elective procedures ($P < .05$).**
Conclusions: **Our long-term EVAR experience indicates that 18% of patients require additional secondary procedures, and most of these patients can be managed by endovascular means with an acceptable overall mortality of 2.9%. Most type I and II endoleaks can be successfully treated by transluminal embolization, and most patients with delayed aneurysm rupture after EVAR can be successfully managed by endovascular or open surgical repair. (J Vasc Surg 2010;52:1442-8.)**

Endovascular aneurysm repair (EVAR) is an acceptable means for treating infrarenal abdominal aortic aneurysms (AAA). However, complications of endoleaks, stent graft migration, stent fracture, aortic neck dilatation, or the development of other aortoiliac aneurysms mandate lifelong patient follow-up, and secondary interventions are required in approximately 15% to 20% of patients.[1,2] Recent advances in stent graft technology and improvement in vascular interventionalists' experience in performing these procedures has certainly led to routine use of EVAR in favorable as well as unfavorable circumstances. The purpose of this current study was to analyze our real-world experience with currently available stent grafts in favorable and unfavorable conditions and report on the outcomes of secondary interventions after EVAR.

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MATERIALS AND METHODS

From 2002 to 2009, 1768 patients underwent EVAR for treatment of 1662 elective (94%) and 106 emergent (6%) infrarenal AAA with a variety of U.S. Food and Drug Administration (FDA) approved and commercially available stent grafts, including the Excluder (W. L. Gore and Assoc, Flagstaff, Ariz), AneuRx (Medtronic, Santa Rosa, Calif), Zenith (Cook, Bloomington, Ind), Talent (Medtronic), and Endologix (Irvine, Calif). The selection for a particular type of stent graft with suprarenal or infrarenal fixation was at the surgeon's discretion. Postoperative follow-up included clinical examination, pulse volume recording, duplex ultrasound imaging, and computed tomography (CTA)/magnetic resonance angiography (MRA) at 1, 6, and 12 months, and yearly thereafter. The need for secondary procedures was defined on the basis of postoperative complications that were confirmed after EVAR, and included the following:

- **All type I and III endoleaks** were treated at the time of diagnosis. Stent graft migration from the proximal fixation site was treated by placement of proximal extension or conversion of the bifurcated stent grafts into aortouniiliac devices with advancement of a second stent graft

within the initial device and a femoral-femoral bypass. When type I endoleaks develop in patients with CTA demonstration of adequate stent graft opposition at the aortic neck, a Palmaz stent (Cordis, Miami Lakes, Fla) was placed at the juxtarenal aorta with partial overlap within the stent graft main body and within the native suprarenal aorta. In select patients, type I endoleaks were also treated with translumbar coil embolization. All type Ib endoleaks from a distal fixation site were treated by coil embolization of the ipsilateral hypogastric artery and stent graft extensions to the external iliac artery. Type III endoleaks were treated with stent graft extensions at the site of endoleak.

- **Type II endoleaks** with evidence of AAA sac growth or a nonshrinking AAA sac >5.5 cm at >6 months after EVAR underwent translumbar or transfemoral coil embolization procedures. Our single-center experience indicates that type II endoleaks are responsible for 15% to 20% of aneurysm ruptures after EVAR. Therefore, our standard practice has been to treat type II endoleaks in large (>5.5 cm) nonshrinking AAA sacs.
- **Endotension** was considered to be a rule-out diagnosis when AAA sac increased in size >5 mm and no obvious endoleak was identified. Treatment was individualized based on the patient's risk factors and included stent graft relining using the low porosity Excluder stent graft, elective conversion to open surgical repair, and in some instances, continued surveillance without any further treatment.
- **Stent graft migration** from the proximal fixation site and type I endoleak was treated with proximal stent graft extensions up to the level of the lowermost renal artery. For persistent type I endoleaks, a Palmaz stent was placed at the aortic neck. Patients with stent graft migration from the proximal fixation site without the presence of type I endoleak underwent proximal stent graft extension if the migration was >10 mm and the remaining stent graft to aortic neck wall opposition was <10 mm. None of the patients with stent graft migration had surgical conversion and stent graft explant as their initial treatment.
- **Symptomatic stent graft limb occlusion** was preferably treated by a femoral artery cutdown and stent graft limb thrombectomy. Our standard approach was to reline the thrombectomized iliac limb with a new iliac stent graft limb as often there is some residual clot burden in the iliac limbs, and findings of concomitant significant external iliac artery stenosis were treated with a self-expanding bare metal stent. A femoral-femoral crossover bypass was reserved for instances when the patient had chronic limb occlusion or attempted stent graft limb thrombectomy was unsuccessful.
- **Symptomatic stent graft limb stenosis** was treated by percutaneous placement of self-expanding or balloon-expandable bare-metal stents at the site of critical stenosis.
- **Iliac aneurysm formation** adjacent to iliac stent graft limbs in patients with prior EVAR underwent treatment if the iliac aneurysm maximum diameter was >3 cm or if failure of the stent graft seal at the distal fixation site resulted in a type Ib endoleak. Patients underwent coil embolization of the ipsilateral hypogastric artery with stent graft extensions to the external iliac artery.
- **AAA rupture after EVAR** required secondary interventions that were endovascular or surgical, or both. The approach was individualized and based primarily on the patient's anatomical suitability for EVAR at the time of aneurysm rupture. Regardless of the patient's hemodynamic status, anatomically suitable patients with ruptured AAA underwent an EVAR-first approach, and treatment was tailored according to the cause of the stent graft failure. The criteria to determine suitability for redo EVAR were based on a detailed evaluation of the CTA, which was used to identify the underlying etiology of stent graft failure. The CTA findings were used to determine the feasibility of using proximal or distal extensions, with or without Palmaz stent placement, and the underlying etiology for stent graft failure was treated. Aortic occlusion balloons during the secondary or redo EVAR were used as needed in hemodynamically unstable patients. When the ruptured AAA after EVAR was not considered anatomically suitable for secondary or redo EVAR, the patient underwent open surgical conversion through a left retroperitoneal approach. In AAA rupture patients with infrarenal stent grafts, aortic clamps were generally placed at the suprarenal level, the aneurysm sac was opened, the entire infrarenal stent graft was explanted, including the iliac limbs, and aortoiliac reconstruction was performed as needed. If the iliac limbs could not be explanted due to scarring, the distal anastomosis was constructed beyond the iliac stent grafts and the aortic bifurcation over sewn, or the limbs were transected at the aortic bifurcation and aortic tube grafts were sutured directly to the distal aortic bifurcation. Supraceliac aortic control was obtained in AAA rupture patients with suprarenal stent grafts. Transaction of the stent graft within the proximal aortic neck was primarily considered in such cases, and the remainder of aortoiliac reconstruction was performed as needed.

Table I. Secondary procedures after endovascular aneurysm repair

Secondary procedures	*No. (%)*
Total, No.	339
Type I endoleak	51 (15.0)
Type II endoleak	136 (40.1)
Type III endoleak	5 (1.5)
Endotension	8 (2.4)
Stent graft migration	46 (13.6)
Limb stenosis/thrombosis	25 (7.4)
Iliac aneurysm formation	39 (11.5)
Aneurysm rupture	29 (8.6)

Data on primary EVAR as well as secondary and tertiary interventions and their outcomes were prospectively collected in a vascular registry and all variables were analyzed.

Table II. Indications and outcomes of secondary procedures after endovascular aneurysm *(EVAR)* repair

Indication	*No. (%)*	*Secondary procedures*	*No. (%)*	*Mortality No. (%)*
Type I endoleaks	51 (15.0)	Proximal stent graft extension	19 (37.3)	2 (3.9)
		Translumbar coil embolization	20 (39.2)	
		Palmaz stent use at aortic neck	14 (27.5)	
		Spontaneous seal (CT/angiogram)	8 (15.7)	
		Open surgical conversion	5 (9.8)	
Type II endoleaks	136 (40.1)	Translumbar coil embolization	124 (92)	1 (0.7)
		Transfemoral coil embolization	12 (8)	
Type III endoleaks	5 (1.5)	Stent graft extensions	5 (100)	0
Endotension	8 (2.4)	Stent graft relining	6 (75)	0
Stent graft migration	46 (13.6)	Aortic stent graft cuffs	36 (78.3)	1 (2.2)
		Aortouniiliac conversion	10 (21.7)	
Iliac stent graft limb thrombosis	25 (7.4)	Stent graft thrombectomy/relining	11 (44)	1 (4)
		Femoral-femoral bypass	14 (56)	
Iliac aneurysms	39 (11.5)	Iliac EVAR	39 (100)	0
AAA rupture	29 (8.6)	Redo EVAR	13 (44.8)	5 (17.2)
		Open surgical conversion	16 (55.2)	

CT, Computed tomography.

RESULTS

From 2002 to 2009, 1768 patients underwent EVAR for treatment of 1662 elective (94%) and 106 emergent (6%) AAA. The mean age was 74 years (range, 49-97; SD, 9.15 years), the mean AAA size was 5.7 cm (range, 4.5-10.8; SD, 3.24 cm), and comorbidities included coronary artery disease in 1291 (73.0%), hypertension in 1411 (79.8%), diabetes in 264 (14.9%), hypercholesterolemia in 834 (47.2%), chronic obstructive pulmonary disease in 316 (17.9%), and end-stage renal disease requiring dialysis in 152 (8.5%). During a mean follow-up of 34 months (range, 1-96; SD, 30.03 months), 339 patients (19.2%) required additional procedures secondary to aneurysm-related complications. The etiology for these 339 secondary interventions included type I endoleaks in 51 (15.0%), type II endoleaks in 136 (40.1%), type III endoleaks in 5 (1.5%), endotension in 8 (2.4%), stent graft migration proximal fixation site in 46 (13.6%), stent graft iliac limb thrombosis or stenosis in 25 (7.4%), subsequent iliac aneurysm formation in 39 (11.5%), or aneurysm rupture after EVAR in 29 (8.6%; Table I).

All secondary interventions and their outcomes are listed in Table II. There was no statistically significant difference in the need for secondary interventions when elective and emergent EVAR were compared. Nonfatal complications of 339 secondary interventions included myocardial infarction in 5 (1.5%), ischemic colitis requiring colostomy in 3 (0.9%), renal failure requiring dialysis in 2 (0.6%), and wound infections in 7 (2.0%).

- **Type I endoleaks** with and without stent graft migration were treated in 51 of 339 patients (15.0%) by proximal stent graft extensions in 19 (37.3%), translumbar coil embolization in 20 (39.2%), or open surgical conversion with stent graft explants and aortoiliac reconstruction in 5 (9.8%). Balloon-expandable Palmaz stent placement at the aortic neck was required in 14 patients (27.5%), and 8 patients (15.7%) with type I endoleaks sealed spontaneously ≤1 month of diagnosis and did not require any further intervention. At the time of their secondary interventions, seven patients (14%) underwent Palmaz stent placement along with proximal stent graft extensions in five (10%) and coil embolization in two (4%). Two patients (3.9%) died: an aortoenteric fistula developed in one patient with translumbar coil embolization who died of complications of the procedure, and one patient with prior stent graft and a Palmaz stent died after stent graft explant and aortoiliac reconstruction.
- **Type II endoleaks** were treated in 136 of 399 patients (40.1%) by translumbar coil embolization in 124 (92%) or transfemoral coil embolization in 12 (8%). One patient (0.7%) died secondary to complications of stent graft and aneurysm sac infection 6 months after the procedure.
- **Type III endoleaks** were treated in 5 of 339 patients (1.5%) by stent graft extensions at the site of endoleak. Four (80%) patients had displacement of stent graft-stent graft overlap, and stent graft fabric tear was presumed in one patient (20%). There were no major complications or deaths.
- **Stent graft migration** from the proximal fixation site was treated in 46 of 339 patients (13.6%), and 19 (41.3%) had associated type I endoleaks. Stent graft migration from the proximal fixation site was treated with stent graft extensions using aortic cuffs in 36 (78.3%). The Excluder stent graft main body was used in 10 (21.7%) to convert bifurcated stent grafts into aortouniiliac devices and a femoral-femoral bypass was performed. One (2.2%) postoperative death occurred secondary to cardiac complications.
- **Iliac stent graft limb thrombosis or stenosis** was treated in 25 of 339 patients (7.4%) by stent graft thrombectomy and relining with a new iliac stent graft limb in 11 (44%) or femoral-femoral bypass in 14 (56%). One patient (4%) with complications of infection and multisystem organ failure died.

Table III. Mortality rate of secondary procedures after endovascular aneurysm repair *(EVAR)*: Rupture vs nonrupture

	Secondary procedures after EVAR			P
	For nonrupture	*For rupture*		
Mortality	17.2% (5/29)	1.6% (5/310)		<.05
		Urgent repair	*Elective repair*	
		4.6% (4/87)	0.4% (1/223)	<.05

Table IV. Endovascular vs surgical secondary interventions based on presentation

Presentation	*Nonrupture after EVAR*	*Rupture after EVAR*	P
Redo EVAR	98.8% (296/310)	44.8% (13/29)	<.001
Open surgical conversion	1.2% (14/310)	55.2% (16/29)	<.001

EVAR, Endovascular aneurysm repair.

- **Iliac aneurysms** developed in 39 of 339 patients (11.5%) during a mean follow-up of 34 months and required coil embolization of the hypogastric artery and stent graft extension to the external iliac artery. There were no major complications or deaths.
- **Delayed AAA rupture after EVAR** occurred in 29 of 339 patients (8.6%) during a mean follow-up of 29 months and was treated by redo-EVAR in 13 (44.8%) or open surgical conversion in 16 (55.2%). The etiology contributing to aneurysm rupture included type I endoleak with stent graft migration in 19 patients (65.5%), type II endoleaks in 6 patients (20.7%), and undetermined etiology in 4 patients (13.8%). Redo EVAR procedures were performed in 13 of 29 patients (44.8%), and open surgical conversions with stent graft explants and aortoiliac reconstructions were performed in 16 patients (55.2%). Although the 30-day mortality of redo EVAR was 7.8% vs 25% for surgical conversion, this difference was not statistically significant.
- **Repeat secondary procedures** were required in an additional 37 of 339 patients (10.9%) at a mean follow-up of 8 months after the initial intervention. These included translumbar coil embolization in 14 (37.8%) for treatment of type I endoleak in 3 (21.4%) or type II endoleak in 11 (78.6%), proximal stent graft extension for migration in 11 (29.7%), distal iliac stent graft extensions in 5 (13.5%), and elective conversion to open surgical repair in 7 (18.9%). There were no major complications or deaths in this group. A comparison of mortality from secondary procedures after EVAR indicates that, as expected, the outcomes in nonruptured aneurysm patients is significantly better than in ruptured AAA patients (17.2% vs 1.6%, $P < .05$), and urgent secondary procedures have a higher mortality compared with elective secondary procedures (4.6% vs 0.4%, $P < .05$) in patients with nonrupture after EVAR (Table III). Furthermore, secondary endovascular procedures were performed in a significantly higher number of patients with nonruptured AAA after EVAR compared with patients with rupture after EVAR (Table IV).

DISCUSSION

Our single-center real-world experience of treating elective and emergent AAA with favorable and unfavorable morphology indicates that after the initial EVAR, the clinical success at a mean of 34 months is 80.8% and the need for secondary procedures is 19.2%. The factors influencing the rate of secondary procedures include vigilance and duration of patient follow-up and the decision for reintervention. In our experience, the indication for secondary procedures from the highest to the lowest frequency were type II endoleaks (40.1%), type I endoleaks with stent graft migration (20.6%), subsequent iliac aneurysm formation (11.5%), AAA rupture after EVAR (8.6%), significant stent graft migration without evidence of type I endoleak (8.0%), symptomatic iliac stent graft limb stenosis or thrombosis (7.4%), endotension (2.4%), and type III endoleaks (1.5%). These data provide several key observations:

1. The mortality rate associated with these secondary procedures was significantly higher for AAA rupture after EVAR (17.2%) than nonrupture (1.6%; $P < .05$).
2. When patients with nonruptured EVAR required urgent secondary procedures such as treatment of type I and III endoleaks, stent graft migration, and iliac limb thrombosis, the mortality (4.6%) was significantly higher than for elective procedures such as treatment of type II endoleaks and endotension (0.4%; $P < .05$).
3. A significantly higher percentage of patients requiring secondary interventions for nonruptured AAA after EVAR can be managed by endovascular means compared with patients who present with rupture after EVAR (98.8% vs 44.8%, $P < .001$; Tables III and IV).

When secondary interventions are required for EVAR failure, there are a variety of reasons and means of treatment

that depend not just on the accepted standards but also on local expertise in dealing with the stent graft failures.[3,4] Initially in our experience, when we treated type I endoleaks, we performed the standard and justified procedures of proximal stent graft extensions with and without the use of Palmaz stents at the aortic neck. Patients with persistent type I endoleak regardless of proximal extensions and Palmaz stent that were at high risk for open surgical conversion underwent translumbar arteriogram and embolization for treatment of type I endoleak. This procedure was successful in eliminating type I endoleak in 70% (14 of 20) of patients. The technique for this translumbar procedure is similar to that when treating type II endoleaks: once in the aneurysm sac the catheter is directed toward the endoleak channel at the aortic neck and coils are packed densely at the endoleak track.

None would argue the benign nature of type II endoleak in face of an AAA sac that has decreased in size after EVAR. However, there has been an increasing recognition during the past several years of increased adverse events in patients with type II endoleaks and nonshrinking as well as enlarging AAA sacs.[5] Although earlier European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) data suggested all type II endoleaks were benign, more recent publications have reported that patients with type II endoleaks have an increased composite adverse event rate of 55% compared with 15% for those without type II endoleaks ($P < .05$).[6] In treating AAA with type II endoleaks with sac growth and stable sac size of >5.5 cm at >6 months, we have routinely adopted the translumbar embolization technique and found this was successful in eliminating the type II endoleak in two-thirds of the patients; the transfemoral approach is generally reserved for translumbar failures. Historically, on the basis of earlier data, some would argue that type II endoleaks without enlarging AAA sacs should be left untreated, and if one were to adopt that approach, the overall incidence of secondary procedures after EVAR would be considerably less than ours at 19.2%, because 40% of our patients had secondary interventions for type II endoleaks. We cannot provide further information on type II endoleaks with and without enlarging AAA sacs, which is a limitation of this data set.

Type III endoleaks are fairly infrequent events and should be treated when diagnosed. The most common methods include stent grafts extensions, mostly iliac stent graft limbs, at the site of stent graft separation. Rarely, stent graft component separation results in the need for conversion of bifurcated stent grafts into aortouniiliac devices or open surgical conversion. Endotension is considered to be a rule-out diagnosis, and is usually made when CTA, duplex ultrasound imaging, and arteriography fail to indicate any endoleaks in the presence of an enlarging AAA sac. To some extent, all currently available devices have various porosities that can contribute to AAA sac growth without evidence of endoleak, and treatment should be individualized according to the patient's risk factors for various procedures. When porosity is suspected to be the culprit of AAA sac growth without evidence of any endoleaks, stent graft relining has been shown to be of value in halting sac growth.[7,8]

The standard accepted treatment for stent graft migration associated with type I endoleak involves securing the seal at the aortic neck with stent graft extensions, as needed. The type of proximal stent graft extension depends on the aortoiliac morphology, the etiology for stent graft migration, and the relationship between the stent graft and the aortic neck, and it is for these reasons that conversion of bifurcated stent grafts into aortouniiliac devices and femoral-femoral bypass are sometimes needed.[9]

Treatment of stent graft migration without an identifiable type I endoleak remains controversial. We reserved treatment of stent graft migration without type I endoleak when several criteria were met, including (1) when stent graft migration was noted in patients with complex aortic necks, and (2) the stent graft migration was >10 mm, and (3) the remaining stent graft to aortic neck wall opposition was <10 mm, in AAA >5 cm. In our experience, 59% of patients with significant stent graft migration did not have an identifiable type I endoleak, and all underwent successful proximal extensions without any notable morbidity and mortality; this would account for 1.5% (27 of 1768) of all EVAR patients.

Secondary procedures for iliac limb thrombosis accounted for 1.4% (25 of 1768) of all EVAR patients, and 44% of these patients who underwent successful redo EVAR procedures with the stent graft iliac limb underwent thrombectomy. We routinely relined with a new iliac stent graft limb, although it is not clear if that would be an absolute necessity. After thrombectomy, when stent graft limbs are noted to have strictures/kinks, or when the outflow has identifiable stenosis, based on our experience we would recommend treatment directed toward the potential underlying etiology for stent graft thrombosis. Of the 25 patients who underwent treatment for iliac stent graft limb thrombosis, one death occurred secondary to postoperative myocardial infarction. One can use stent grafts, bare metal balloon-expandable, or self-expanding stents to treat these lesions, although data evaluating these procedures are lacking.

The fundamental goal of AAA repair by surgical or endovascular means is to reduce the risks for aneurysm rupture and death. However, none of the currently available devices are completely effective in preventing aneurysm rupture after EVAR, and lifelong surveillance of these stent grafts and aneurysms is needed. In our experience, patients presenting with aneurysm rupture after EVAR tend not to exhibit profound signs of hemodynamic collapse, and their symptoms are generally that of abdominal and back pain. As long as the patients maintain a measurable blood pressure, the techniques of hypotensive hemostasis by limiting the resuscitation to maintain a detectable blood pressure can help minimize ongoing hemorrhage. Detailed evaluation of the CTA to identify the etiology of stent graft failure and aneurysm rupture is vital for planning for redo EVAR. The placement of the stent graft extensions—proximal, distal, or within the stent graft components to achieve stent graft fixation and seal and treat the ruptured aneurysm—is done on the basis of the CTA and intraoperative arteriogram findings, and endovascular therapy is targeted toward the underlying etiology for stent graft failure.

As expected, the most common adverse factors contributing to aneurysm rupture after EVAR included type I endoleak (65%). What was unexpected was that type II endoleaks were the only notable findings and were considered responsible for 21% of AAA ruptures after EVAR, and in 14% of patients, the etiology for AAA rupture was undetermined. Redo EVAR procedures were performed in 13 of 29 patients (44.8%), and open surgical conversions with stent graft explants and aortoiliac reconstructions were performed in 16 patients (55.2%). The 7.8% mortality rate for the redo EVAR group was better than the 25% rate in the open surgical conversion group, although this difference was not statistically significant. Delayed AAA rupture after EVAR can be successfully managed in most patients by open surgical conversion or redo EVAR. The approach to each patient should be individualized. Complete stent graft explant is not necessary in most patients, and a secondary EVAR for delayed AAA rupture, with or without an elective conversion to open surgical repair, remains an option. In 29 patients that presented with aneurysm rupture, the overall mortality was 17.2%, and all 5 patient deaths were secondary to cardiovascular collapse and multiorgan system failure.

We preferentially use the retroperitoneal approach for treatment of ruptured AAA in patients requiring open surgical conversion, and this also has been our standard approach for managing AAA rupture after EVAR. If the etiology of the aneurysm rupture is secondary to type I, II, or III endoleak and can be determined by a preoperative CT scan, the surgeon may have some foresight into the further options for subsequent revascularization. Often the etiology of the aneurysm sac rupture is only determined after the aortic sac is opened. Kelso et al[10] reported their experience of 41 stent graft explants after EVAR and found the mortality was significantly higher for ruptured vs nonruptured aneurysms (66% vs 9%).[10]

Our single-center experience at The Vascular Institute for Health and Disease in Albany is the largest contemporary series to date that analyzes the outcomes of real-world experiences with EVAR using currently available third- and fourth-generation stent grafts. Our findings remain consistent with several other reports highlighting the need for repeat interventions after EVAR and the need for lifelong surveillance after EVAR. Our purpose was to analyze the real-world EVAR experience. Stent graft technology has undergone significant evolution in the past decade, with changing indications for use per device. Unfortunately, we did not have the data on indications for use for each device, and therefore, we did not analyze the percentage of failures by device but, rather, focused on the outcomes of secondary interventions after EVAR when needed, regardless of the device type:

- Abbruzzsese et al[11] evaluated their experience of device-specific long-term outcomes of 565 elective EVAR patients treated during a 7-year period ending in 2005. Their findings indicated that although the reintervention rate was comparable among various FDA-approved devices, stent graft application outside the indications for use had a negative effect on late results.
- Pitoulias et al[12] reported 625 elective EVAR, indicating that 16.2% of patients required secondary procedures during a mean follow-up of 47 months; the mortality rate of their patients undergoing emergent secondary procedures was substantially higher than that of elective procedures (8.8% vs 20%).
- Verhoeven et al[13] reported similar findings of 308 EVAR patients, indicating a reintervention rate of 15%; two-thirds were elective and one-third emergent, with 80% of the patients undergoing a successful endovascular secondary intervention and the overall open surgical conversion rate of 3%.
- Becquemin et al[14] evaluated their 8-year experience of 250 EVAR patients and reported a secondary intervention rate of 27% at a mean follow-up of 19 months and had similar findings indicating that the secondary interventions did not lead to increased mortality, rather more surgical conversions and a higher clinical failure rate.

CONCLUSIONS

Our long-term experience indicates that approximately 19% of patients require additional second and third procedures, and almost all of these patients can be managed by endovascular means with acceptable overall morbidity and mortality. Translumbar coil embolization can be used as an adjunctive procedure for treating type I endoleaks. Most patients with delayed aneurysm rupture after EVAR can be successfully managed by endovascular or open surgical repair with comparable mortality. Aggressive management of late complications may minimize the mortality associated with this procedure.

AUTHOR CONTRIBUTIONS

Conception and design: MM
Analysis and interpretation: MM, SPR
Data collection: MM, KO
Writing the article: MM, PP
Critical revision of the article: YS, MM
Final approval of the article: MM, JT
Statistical analysis: MM, PK
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DISCUSSION

Dr Marc A. Passman (*Birmingham, Ala*). I would like to congratulate Dr Mehta and his colleagues from Albany, New York, on an excellent paper, and applaud the program committee for inviting some cross-regional work onto our Southern Association for Vascular Surgery (SAVS) program. Over an 8-year experience, the group from Albany performed 1768 endovascular abdominal aortic aneurysm (AAA) repairs, of which 19.2%, or almost 1 in 5, required some secondary or tertiary procedure. Interestingly, we just reviewed our endovascular experience at University of Alabama at Birmingham (UAB), which will be presented at another vascular meeting later this year. Over a similar time period representing about 1100 stent graft repairs, in our experience only 9.2%, or 1 in 10, required a secondary procedure, a rate less than half of what was presented here. I will try to avoid the tempting regional comparison that perhaps we know how to do endovascular AAA repairs more definitively in our Southern region compared with the great state of New York. Rather, there are likely some differences in our respective experiences that form the focus of my questions.

First, you state in the manuscript that stent grafts were performed in both "favorable and unfavorable" conditions, but no further definition or analysis is provided. Assuming what you term "unfavorable conditions" relates to more anatomically challenging situations, were you able to stratify your data set of secondary procedures within the larger overall endovascular aneurysm repair population to determine if use in "unfavorable conditions" was a predictor for stent graft failure and the need for secondary procedure?

Second, because 40% of your secondary procedure needs were for type II endoleak, much of your data analysis is driven by this dominant subgroup. Perhaps the overall larger need for secondary procedures in your study is in part reflective of a more aggressive approach for type II endoleaks. What percentage of the larger overall endovascular aneurysm repair population had type II endoleaks, and what percentage of these type II endoleaks required a secondary procedure? Please clarify what criteria are used to intervene for a type II endoleak within your group and if indeed your approach is more aggressive.

Third, with such a large group of vascular surgeons within the Albany practice, was there some degree of surgical variability or perhaps surgeon outliers that accounted for a larger portion of failed primary endovascular stent graft repairs or need for secondary procedures?

Fourth and finally, with such a large reported experience over an extended time period, there is an opportunity here to look at time-dependent data. Have you had a chance to look at any time-dependent clustering patterns relating to when the need for secondary procedures may arise and what type of secondary procedure was required at that time point?

Again, all regional considerations aside, I wish to welcome the group from Albany to our meeting and appreciate the opportunity to discuss this paper.

Dr Manish Mehta. On behalf of The Albany Vascular Group I would like to thank the Southern Association of Vascular Surgery for extending us an invitation. Furthermore I would like to thank Dr Passman for discussing this paper. Marc, I appreciate your insightful questions and comments. Your question whether we can predict stent graft failures based on favorable versus unfavorable conditions is a good one, and currently available data would suggest that when we treat patients that meet the IFUs for a particular stent graft, the outcomes tend to be better than patients that fall outside the IFUs, ie short necks, short/angulated necks, etc. I can tell you that less than 50% of our aneurysm patient population would meet the IFUs to be enrolled in currently ongoing stent graft trials, and would be considered to have favorable anatomy.

Unfortunately we did not quantify morphological variables that would allow us to analyze IFUs per stent graft and match them to anatomically favorable versus unfavorable characteristics in our patient population. The goal of our study was to analyze the outcomes of secondary procedures following endovascular aneurysm repair. Treatment of type 2 endoleaks remains a controversial issue. At Albany, we have reserved treating type 2 endoleaks in patients with aneurysm sac size increase of greater than 5mm following EVAR, and in large abdominal aortic aneurysms greater than 5.5cm with persistent type 2 endoleaks at greater than 6 months after EVAR. This is a reflection of our experience discovering that up to 20% of aneurysm ruptures following EVAR are secondary to type 2 endoleaks. Furthermore, there have been several recent papers suggesting that patient with persistent type 2 endoleaks tend to have worse outcomes over long term follow up. The translumbar approach for embolization of these endoleaks is a relatively benign procedure, and so we have considered this as a viable option in select patients.

To answer your question regarding the surgical variability of a large number of vascular surgeons in Albany, as you know we have 17 vascular surgeons, but as you also know, we pride ourselves in developing structured standardized approaches to all procedures whether they are distal bypass, carotid endarterectomy, or endovascular repair. I think that overall we did not analyze the surgical variability amongst different partners, and the need for secondary procedures following EVAR, but my sense would be that there really would not be much of a difference since we all perform these procedures in a very similar manner.

Lastly, with regards to time dependence, initially I thought that as we got more experienced, patients would need less secondary interventions. What I think is happening is that with gaining significant experience, we are also treating more complex aortoiliac aneurysms by endovascular means, and this would mean that the incidence of secondary interventions following EVAR might not change with increasing experience. The important point that we have learned here is that the risks of secondary interventions are little under controlled elective circumstances, when compared to emergent circumstances, so vigilant patient follow up remains a vital component of endovascular aneurysm therapy.